JUN 11 2003

Nano-TiCrown ™ Premarket Notification By Nano-Write Corporation

K031627

Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR807.92.

1.0.1 SUBMITTER INFORMATION

Company Name:	Nano-Write Corporation
Company Adress:	2021 Las Positas Court, Suite 121
	Livermore, CA 94551
Company Phone:	925-606-1388 [FAX: 925-606-1371]
e-mail	knappnwc@sbcglobal.net
Contact Person:	Kenneth E. Knapp, Chief Executive Officer
Date Summary Prepared:	April 30, 2003

1.1 DEVICE IDENTIFICATION

Trade/Proprietary Name:	Nano-TiCrown ™
Classification Name:	Base Metal Alloy
	21 CFR 872.3710
Product Code:	76 EJH
Device Class & Panel:	Class II (non-exempt) Device, Dental Specialty Panel

1.2 INDICATIONS FOR USE:

This device entitled: **Nano-TiCrown ™ Titanium Metal Alloy Dental Device** (aka: **Nano-TiCrown™**) is a Titanium/Titanium Nitride based alloy intended for use as a base metal alloy in the making of single unit device porcelain-fused-to-metal (PFM) prosthetic dental materials and custom-made dental prosthetic devices, such as a porcelain-to-metal veneer for a tooth. The **Nano-TiCrown ™** is intended to be used as a single unit coping device, i.e., a PFM dental restorative device, and this device is not intended for use on metal only or other non-ceramic porcelain restorations. **Nano-TiCrown ™** is a **Class II** (non-exempt) medical device that is described within the **Dental Products** medical specialty panel of the U.S. Food and Drug Administration (FDA), under FDA Regulation Number **21 CFR 872.3710**, and Product Code: **EJH**. The **Nano-TiCrown ™** device is recommended for all anterior and posterior tooth dental crown restorations. This Titanium/Titanium Nitride coping device (**i.e., Nano-TiCrown ™**) is to be used by dental laboratories in the fabrication of PFM dental crowns for dentists, This **Nano-TiCrown ™** is intended to be marketed to medical professionals and for point-of-care use, and is not intended for sale over-the-counter in its current design. **[Warning: This device should be used with caution where the patient has known metal allergies and specifically is not intended to be used where known patient allergies to Titanium exist].**

1.3 IDENTIFICATION OF PREDICATE DEVICES

Code/Class	Device Name	510(k)	Applicant	DATE CLEARED
EJH/II	(CP) Titanium and Ti6Al-4V Alloy for Fixed Prosthesis	K901552	Nobelpharma USA	06/24/1991
EJH/II	DC TITAN	K001798	Austenal Inc.	07/31/2000

1.4 DEVICE DESCRIPTION

The Nano-TiCrown ™ Titanium/Titanium Nitride dental coping substructure for full fused porcelain to metal PFM devices, consists of a Titanium/Titanium Nitride substructure. The Nano-TiCrown ™ device is intended to be used in single unit coping dental restorative devices with full porcelain to metal coverage for PFM devices.

1.5 TECHNOLOGICAL CHARACTERISTICS

The different Nano-TiCrown ™ Technological Characteristics compared to the predicate devices do not diminish the safety and effectiveness or pose any known adverse effects. This conclusion is based on the performance data including, mechanical, chemical and cytotoxicity biological tests, which meet or exceed the intended use specification ISO 9693:1999(E), specification for "Metal-Ceramic dental restorative systems". The Nano-TiCrown ™ is intended to be used as a single unit coping device, i.e., a PFM dental restorative device, and this device is not intended for use on metal only or other non-porcelain restorations. **Caution: This Nano-TiCrown ™ dental coping device is limited to use on a tooth surface consisting of: Vita Titanium™ Ceramic porcelain material only, and has not yet been tested with other dental ceramic porcelains. Further, thic Nao-TiCrown™ coping device material is intended to be used for single tooth restorations.**

1.6 PERFORMANCE DATA

Device performance data meets all of the requirements for chemical, mechanical and biocompatibility as specified in ISO 9693. The performance test data shown in the device performance table is equivalent to that of the predicate devices show above. Additionally, Nano-TiCrown ™ device cytotoxicity biocompatibility test results show, no cell lysis (0) for three tests up to 72 hours, and the results are considered non-toxic. The cytotoxicity tests were performed in accordance with the requirements specified in ISO 10993:1997 (E).

Nano-TiCrown ™ PERFORMANCE DATA

DESCRIPTION	MEASURED MEAN
Ti Coping Composition.	99.8% Titanium, Grade 2*
Titanium Nitride Composition.	$Ti_{.50}N_{.50}$ (atomic concentration)
Coping wall thickness Titanium metal 100μm-350μm.	As specified by Dental Laboratory, end-user.
Coping wall thickness Titanium Nitride.	10μm
Density	4.74 gm/cm^{3}**
Proof Stress	265 Mpa**
Modulus	61 GPa**
Elongation	8.5%**
Coeff. Of Exp. 25-500 °C	$8.8x10^{-6}K^{-1}$**
Porcelain Bond	35Mpa**

*ASTM B 265-02, "Standard Specification for Titanium and Titanium Alloy Strip, Sheet and Plate".

**ISO 9693: 1999(E), "Metal-Ceramic dental restorative systems".

1.7 SUBSTANTIAL EQUIVALENCE

The Nano-TiCrown ™ is substantially equivalent to the predicate devices based on the chemical, mechanical and biocompatibility performance data reported in this 510(k). The chemical, mechanical and biocompatibility performance data meets or exceeds the minimum device requirements for the intended use of the Nano-TiCrown™ device, see ISO 9693:1999(E). Additionally there are no known adverse effects of the Nano-TiCrown™ device. The performance data shows that the safety and effectiveness has not been diminished by the introduction of the Titanium Nitride chemical compound, or by the different Technological Characteristics used to fabricate the Nano-TiCrown ™ device. Based on these test results Nano-TiCrown™ is substantially equivalent (SE), to the predicate devices listed in this 510(k) submission.

1.8 510(k) CHECKLIST [CITE: 21CFR807.87] and APPLICABLE STANDARDS MET

This 510(k) notification submission contains all information as required by 21CFR807.87.

1.8.1 Device Name & Classification Name: Nano-TiCrown ™, Base Metal Alloy

1) Requirements Met- Listed in section 1.1 of this Summary of Safety and Effectiveness and in the Indications for Use Statement , section 2.0 of this 510(k).

1.8.2 Establishment Registration Number:

1) Requirements Met- Applied for on January 2, 2003.

1.8.3 Device Class and Panel: Class II (non-exempt) Device, Dental Specialty Panel

1) Requirements Met-See section 1.1 of this Summary of Safety and Effectiveness.

1.8.4 Requirements of The Act, Section 514, Performance Standards and Data.

1.8.4.1 Performance Standards FDA consensus standards for (EJH)

4) ISO 9693: 1999(E), "Metal-Ceramic dental restorative systems", ref. (11) in this 510(k).

5) ADA/ANSI No. 38:2000, "Metal Ceramic Systems". The same as ISO 9693: 1999(E), not referenced or used in this 510(k).

6) ADA/ANSI No. 14:1982, "Dental Base Metal Casting Alloys", Not Applicable to Titanium Base Metal Alloys. ISO 9693: 1999(E) specifies Titanium base metal property requirements.

1.8.4.1.1 Other Performance Standards (references 12-26 in this 510(k))

1) ASTM B 265-02, "Standard Specification for Titanium and Titanium Alloy Strip, Sheet and Plate".

2) ASTM E-120-00, "standard Test Methods for Chemical Analysis of Titanium/titanium Alloys".

3) ASTM F-1710-97 "Standard Test Method for Trace Metallic Impurities in Electronic Grade Titanium by High Mass-Resolution Glow Discharge Mass Spectrometer".

4) ASTM E-1019-00 "Standard Test Methods for Determination of Carbon, Sulfur, Nitrogen and Oxygen in Steel and in Iron, Nickel and Cobalt Alloys".

5) ASTM E-1409 "Oxygen Determination in Titanium and Titanium Alloys".

6) ASTM E-1937 "Nitrogen Determination in Titanium and Titanium Alloys".

7) ASTM E-1447 "Hydrogen Determination in Titanium and Titanium Alloys".

8) "Analytical Resolution versus Detection Limit", http://www.eaglabs.com,

9) "Rutherford Backscattering Spectrometry (RBS) Analysis of Titanium Nitride and Titanium OxyNitride Films", RBS Application Series NO.2 pages 1-2, Charles Evans & Associates.

10) ISO 6892:1998(E) "Metallic materials-Tensile testing at ambient temperature".

11) ISO 10993-1:1997(E) "Biological evaluation of medical devices-Part1: Evaluation and Testing".

12) ISO 7405: 1997(E), "Dentistry-Preclinical evaluation of biocompatibility of medical devices used in dentistry-Test methods for dental materials".

13) ANSI/ADA Specification NO. 41 Reaffirmed: January 23, 2001, "Recommended Standard Practices for the Biological Evaluation of Dental Materials".

14) ASTM F67-00, "Standard Specification for unalloyed Titanium for Surgical Implant Applications, (UNS R50250, UNS R50400, UNS R50550, UNS R50700".

15) CRC Handbook of Chemistry and Physics, 68th Edition 1987-1988, page B-140.

1.8.4.2 Performance Data, (see section 6.0 of this 510(k):

1) Chemical Composition of Nano-TiCrown ™ Material.

a) Nano-TiCrown™ Titanium chemical composition measurement data meets or exceeds Performance Standards; ISO 9693: 1999(E) and ASTM B 265-02. The Titanium chemical composition measurement data and summary is contained in this 510(k) body.

b) Nano-TiCrown ™, Titanium Nitride (TiN) Exterior Layer Chemical Composition data meets (TiN) CRC publish composition data.

c) The Nano-TiCrown™ Titanium and titanium Nitride chemical composition measurement data and summary are contained in this 510(k) body.

2) Biocompatibility:

a) Nano-TiCrown ™ porcelain fused to metal finished device cytotoxicity biological evaluation scored (0) at 24, 48 and 72 hours and is considered NON-TOXIC. This meets the requirements of standards, ISO 10993-1: 1997(E), "Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing" and ANSI/ADA Specification NO. 41 Reaffirmed: January 23,2001, "Recommended Standard Practices for the Biological Evaluation of Dental Materials".

b) The cytotoxicity biological evaluation measurement data and summary are contained in this 510(k) body.

3) Mechanical Properties:

a) Nano-TiCrown ™ mechanical properties; proof stress of non-proportional elongation and percentage elongation after fracture measurement data meet or exceed that required by ISO 9693: 1999(E).

b) The mechanical property measurement data and summary are contained in this 510(k) body.

4) Solidus and Liquid Temperatures:

   a. Nano-TiCrown™ Titanium melting point value is from CRC publish composition data page B-140, consistent with requirements of ISO 9693: 1999(E).

5) Coefficient Of linear Thermal Expansion:

a) Nano-TiCrown™ coefficient of linear thermal expansion measurement data meets or exceeds the requirements of ISO 9693: 1999(E).

b) The coefficient of linear thermal expansion measurement data and summary are contained in this 510(k) body.

6) Specific Gravity:

a) Nano-TiCrown™ Specific Gravity measurement data meets or exceeds the requirements of ISO 9693: 1999(E).

b) The Specific Gravity measurement data and summary are contained in this 510(k) body.

7) Metal-Ceramic System (debonding/crack-initiation strength).

a) Nano-TiCrown™ with Vita Titanium Ceramic (named ceramic) manufactured by Vita Zahnfabrik H. Raufer GMBH & Co. KG, crack initiation measurement data meets or exceeds requirements of ISO 9693: 1999(E).

b) The crack initiation measurement data and summary are contained in this 510(k) body.

8) Packaging, Marking and Labeling:

a) Nano-TiCrown™ Packaging and labeling meets ISO 9693: 1999(E) requirements and FDA "Labeling requirements-General".

b) The packaging and labeling specification and Insert are contained in this 510(k) body and the non-confidential section of this 510(k).

1.8.5 Labels and Advertisement:

1) Labeling and advertisement met in Summary of Safety and Effectiveness and in non-confidential information and in section 3.0 of this 510(k). Meets FDA guidance document "Labeling requirements-General" and special labeling requirements of standard ISO 9693: 1999(E).

1.8.6 Statement Indicating Similarities and Differences to Predicate Devices and Supporting data:

1) The requirements for a statement indicating device similarities and differences to predicate devices are met and stated in Section 5.0 of this 510(k).

5.0 Predicate Device Comparison

5.1Intended Use Comparison

5.2 Directions for Use Comparison

5.3 Design and Materials Comparison

5.4 Mechanical Properties Comparison

5.5 Biocompatibility Comparison

5.6 Technological Characteristics Comparison

2) Supporting performance data fro the Nano-TiCrown™ is summarized in section 6.0 of this 510(k).

1.8.6.1 Technological Change Justification and Supporting Data

1) The different Nano-TiCrown™ technological characteristics compared to the predicate devices are identified in section 5.0, comparison to predicate devices. The supporting performance data in section 6.0 meets or exceeds the consensus standard requirements shown in 1.8.4.1 of this Summary and other performance standards 1.8.4.1.1. The performance data in section 6.0 indicates that the different technological characteristics used to fabricate the Nano-TiCrown™ device do not diminish the safety and effectiveness, and is considered substantially equivalent (SE) based on the performance data and consensus standard s sated above. Requirements are met within this 510(k).

1.8.7 510(k) Summary or Statement:

1) This 510(k) Summary of Safety and Effectiveness, section 1.0 contained within this 510(k) meets these requirements.

1.8.8 Financial Certification or Disclosure Statement:

1) Not Applicable. This 510(k) does not contain any clinical studies, nor has any clinical studies been requested to any outside testing laboratories or institutions.

1.8.9 Submission Claiming Substantial Equivalence to Class III Device:

1) Not Applicable. This 510(K) does not reference any Class III medical devices.

1.8.10 Truthful And Accuracy Statement:

1) The Truthful and Accuracy Statement is contained within this 510(k) notification submission on page 3, requirements met.

1.9 Additional Information Requested by Commissioner:

1) All original test data and associated information not included in this submission will be available upon request to authorized agents of the U.S. Food and Drug Administration (FDA).

1.9.1 CONCLUSIONS

This 510(k) Premarket notification contains all information required by 21 CFR 807.87. Performance test results and the intended use are Substantially Equivalent (SE) to predicate devices. The Nano-TiCrown™ device performance data shows that the safety and effectiveness has not been diminished and therefore is substantially equivalent (SE), to the predicate devices.

1.9.2 <u>510(k) CONTACT PERSON:</u> For further information, please contact: Kenneth E. Knapp (Chief Executive Officer of Nano-Write Corporation) by mail: 2021 Las Positas Court, Suite 121, Livermore, CA 94551; Telephone: 925-606-1388; Fax: 925-606-1371; e-mail: knappnwc@sbc.global.net

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 11 2003

Nano-Write Corporation
C/O Mr. Alfredo J. Quattrone
Responsible Third Party Official
California Department of Health Services
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, California 94234

Re: K031627
Trade/Device Name: Nano-TiCrown™ Titanium Metal Alloy Dental Device
Regulation Number: 21 CFR 872.3710
Regulation Name: Base Metal Alloy
Regulatory Class: II
Product Code: EJH
Dated: May 27, 2003
Received: May 27, 2003

Dear Mr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

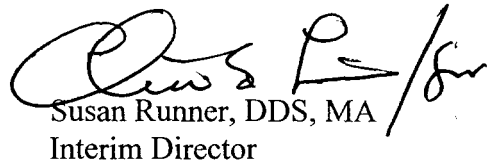
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number _____ (Pending this Submission)

Device Name: Nano-TiCrown ™ Titanium Metal Alloy Dental Device

Indications for Use: This device entitled: **Nano-TiCrown ™ Titanium Metal Alloy Dental Device** (aka: **Nano-TiCrown ™**) is a Titanium/Titanium Nitride based alloy intended for use as a base metal alloy in the making of single unit device porcelain-fused-to-metal (PFM) prosthetic dental materials and custom-made dental prosthetic devices, such as a porcelain-to-metal veneer for a tooth. The **Nano-TiCrown ™** is intended to be used as a single unit coping device, i.e., a PFM dental restorative device, and this device is not intended for use on metal only or other non-ceramic porcelain restorations. **Nano-TiCrown ™** is a **Class II** (non-exempt) medical device that is described within the **Dental Products** medical specialty panel of the U.S. Food and Drug Administration (FDA), under FDA Regulation Number **21 CFR 872.3710**, and Product Code: **EJH**. The **Nano-TiCrown ™** device is recommended for all anterior and posterior tooth dental crown restorations. This Titanium/Titanium Nitride coping device (i.e., **Nano-TiCrown™**) is to be used by dental laboratories in the fabrication of PFM dental crowns for dentists. This **Nano-TiCrown ™** is intended to be marketed to medical professionals and for point-of-care use, and is not intended for sale over-the-counter in its current design. **[Warning: This device should be used with caution where the patient has known metal allergies and specifically is not intended to be used where known patient allergies to Titanium exist].**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulley for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031627

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)